## STATUTORY INSTRUMENTS

## 2023 No. 171

The National Health Service (Amendments Relating to Pre-Payment Certificates, Hormone Replacement Therapy Treatments and Medicines Shortages) Regulations 2023

## New regulation 55A of the GMS Regulations

12. After regulation 55 of the GMS Regulations(1) (prescribing: general), insert—

## "Prescribing software and supply shortages etc. of medicines

- **55A.**—(1) This paragraph applies where—
  - (a) the Secretary of State, in the exercise of the Secretary of State's obligations, duties or powers in respect of ensuring that adequate supplies of English health service medicines are available—
    - (i) has acquired information under Part 6 of the Health Service Products (Provision and Disclosure of Information) Regulations 2018(2) (information about price and availability of health service medicines) about a particular English health service medicine, and
    - (ii) authorises the disclosure of information derived from that information ("relevant communications information") to contractors for the purpose of ensuring, by the appropriate and effective management of—
      - (aa) a supply shortage of that particular English health service medicine, or
      - (bb) the discontinuation of the production of that particular English health service medicine,

that adequate supplies of English health service medicines are available;

- (b) the contractor wishes to receive relevant communications information via the prescribing software that it has to support the issuing of prescriptions for English health service medicines (in addition to the other ways in which it may access that information); and
- (c) there is a software programme available to the contractor from its supplier of prescribing software ("SPS") that would enable that.
- (2) Where paragraph (1) applies, the contractor must ensure that the arrangements it makes with a SPS to support the issuing of prescriptions for English health service medicines—
  - (a) include appropriate provision requiring the updating of the software to take account of relevant communications information about supply shortages of, or the discontinuation of the production of, particular English health service medicines; and

<sup>(1)</sup> Amended by S.I. 2019/1137.

<sup>(2)</sup> S.I. 2018/677.

- (b) are, as regards that inclusion, consistent with the authorisation referred to in paragraph (1)(a)(ii).
- (3) The disclosure of relevant communications information by the Secretary of State or a person acting on the Secretary of State's behalf to a SPS, or by a SPS to a contractor in a manner that is consistent with the authorisation referred to in paragraph (1)(a)(ii), is not a disclosure of confidential or commercially sensitive information affected by section 264B(2)(b) of the Act, in a case where but for this paragraph it would be, if the disclosure is—
  - (a) for the purpose of ensuring, by the appropriate and effective management by the Secretary of State (and persons acting on the Secretary of State's behalf) of—
    - (i) a supply shortage of the particular English health service medicine in question, or
    - (ii) the discontinuation of the production of the particular English health service medicine in question,

that adequate supplies of English health service medicines are available; and

- (b) proportionate to that purpose.
- (4) A disclosure of relevant communications information as mentioned in paragraph (3) may be by way of permitting access to that information rather than proactive disclosure.
- (5) A disclosure of relevant communications information that is as mentioned in paragraph (3) is to be treated as neither constituting a breach of confidence nor prejudicing commercial interests in any case where, but for this paragraph, it would be so treated.
- (6) Section 264B(3)(f) of the Act applies to the contractor in respect of relevant communications information received as part of the arrangements mentioned in paragraph (2) as it would if the Secretary of State had disclosed that information to the contractor directly instead of via an intermediary.
- (7) A SPS must not disclose relevant communications information, other than as provided for in paragraph (3), if it is confidential or commercially sensitive information that, when disclosed to a contractor by the Secretary of State, is subject to the disclosure restriction in section 264B(2)(b) of the Act.".